K131351

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hkatz@AlfaWassermannUS.com Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	AUG 15 2013
Date Summary Prepared:	July 3, 2013	
Device:	Trade Name:	ACE Alkaline Phosphatase Reagent
	Classification:	Class 2
	Common/Classification Name:	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (21 C. F.R. § 862.1050) Product Code CJE
	Trade Name:	ACE Amylase Reagent
	Classification:	Class 2
	Common/Classification Name:	Saccharogenic, Amylase (21 C. F.R. § 862.1070) Product Code CIJ
	Trade Name:	ACE ALT Reagent
	Classification:	Class 1
	Common/Classification Name:	NADH Oxidation/NAD Reduction, ALT/SGPT (21 C.F.R. § 862.1030) Product Code CKA
	Trade Name:	ACE AST Reagent
	Classification:	Class 2
	Common/Classification Name:	NADH Oxidation/NAD Reduction, AST/SGOT (21 C.F.R. § 862.1100) Product Code CIT
Predicate Devices:	Manufacturer for reagent system predicates: Alfa Wassermann ACE and ACE Axcel Clinical Chemistry Systems and ACE Reagents (K113253, K931786, K930104, K113436, K113382)	

Device Descriptions:	In the ACE Alkaline Phosphatase Reagent assay, alkaline phosphatase catalyzes the hydrolysis of colorless p-nitrophenyl phosphate to p-nitrophenol and inorganic phosphate. In an alkaline solution (pH 10.5), p-nitrophenol is in the phenoxide form and has a strong absorbance at 408 nm. The rate of increase in absorbance, monitored bichromatically at 408 nm/486 nm, is directly proportional to the alkaline phosphatase activity in the sample. In the ACE Amylase Reagent assay, α-amylase hydrolyzes the 2-chloro-p-nitrophenyl-α-D-maltotrioside substrate to release 2-chloro-p-nitrophenol and form 2-chloro-p-nitrophenyl-α-D-maltoside, maltotriose and glucose. The rate of increase in absorbance, monitored bichromatically at 408 nm/ 647 nm, is directly proportional to the α-amylase activity in the sample. In the ACE ALT Reagent assay, alanine aminotransferase converts the L-alanine and α-ketoglutarate substrates in the reagent to L-glutamate and pyruvate, respectively. Lactate dehydrogenase (LDH) catalyzes the oxidation of the reduced cofactor to the cofactor. The rate of conversion of the reduced cofactor to the cofactor can be determined by monitoring the decrease in absorbance bichromatically at 340 nm/647 nm. This rate of conversion from the reduced cofactor to the cofactor is a function of the activity of ALT in the sample. In the ACE AST Reagent assay, aspartate aminotransferase converts the L-aspartate and α-ketoglutarate in the reagent to oxaloacetate and L-glutamate, respectively. The oxaloacetate undergoes reduction, with concurrent oxidation of NADH to NAD^+ in the malate dehydrogenase-catalyzed indicator reaction. NADH absorbs strongly at 340 nm, whereas NAD^+ does not. Therefore, the rate of conversion of NADH to NAD^+ can be determined by monitoring the decrease in absorbance bichromatically at 340 nm/647 nm. This rate of conversion from NADH to NAD^+ is a function of the activity of AST in the sample. Lactate dehydrogenase is added to prevent interference from endogenous pyruvate, which is normally present in blood.
Intended Use:	Indications for Use: The ACE Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE Amylase Reagent is intended for the quantitative determination of α-amylase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas). This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Intended Use:	The ACE ALT Reagent is intended for the quantitative determination of alanine aminotransferase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Alanine aminotransferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE AST Reagent is intended for the quantitative determination of aspartate aminotransferase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Measurements of aspartate aminotransferase are used in the diagnosis and treatment of certain types of liver and heart disease. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.
Technological Characteristics:	The ACE Alkaline Phosphatase Reagent is composed of two reagent bottles (Buffer and Substrate Reagent). The reagents contain AMP Buffer (pH 10.45), magnesium acetate, and p-nitrophenyl phosphate. The ACE Amylase Reagent is composed of a single reagent bottle. The reagents contain 2-chloro-p-nitrophenyl-α-D-maltotrioside, sodium chloride, calcium acetate, potassium thiocyanate, and MES buffer (pH 6.0). The ACE ALT Reagent consists of two reagent bottles (Substrate and Coenzyme). The reagents contain L-alanine, α-ketoglutarate, nicotinamide adenine dinucleotide-reduced (NADH), lactate dehydrogenase, and Tris buffer. The ACE AST Reagent consists of two reagent bottles (Substrate and Coenzyme). The reagents contain L-aspartate, α-ketoglutarate, nicotinamide adenine dinucleotide-reduced (NADH), malate dehydrogenase, lactate dehydrogenase, and Tris buffer.

Device Comparison with Predicate

Comparison of similarities and differences with predicate device

ACE Alkaline Phosphatase Reagent

ALP	Candidate Device	Predicate Device K931786 (ACE ALP)
Intended Use/ Indications for Use	The ACE Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	SA2002: 20 Days RX2002: 7 Days	Same
Sample Type	Serum and lithium heparin plasma	**Serum**
Sample Volume	4 µL	Same
Reaction Volume	169 µL	Same
Expected Values	44 - 147 U/L	Same
Measuring Range	9 - 1400 U/L	Same
Sample Stability	Serum ALP is stable for 7 days at 4-8°C and for 2 months at -20°C	Same

ACE Amylase Reagent

AMYLASE	Candidate Device	Predicate Device K931786 (ACE Amylase)
Intended Use/ Indications for Use	The ACE Amylase Reagent is intended for the quantitative determination of α-amylase activity.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	**Serum**
Sample Volume	3 µL	Same
Reaction Volume	168 µL	Same
Expected Values	20 - 104 U/L	Same
Measuring Range	9 - 1900 U/L	Same
Sample Stability	Serum amylase is stable for 7 days at room temperature (18-26°C) and at 4°C for one month. Recommended storage is at 4°C.	Same

Device Comparison with Predicate

ACE ALT Reagent

ALT	Candidate Device	Predicate Device K930104 (ACE ALT)
Intended Use/ Indications for Use	The ACE ALT Reagent is intended for the quantitative determination of alanine aminotransferase activity concentration.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	**Serum**
Sample Volume	13 µL	Same
Reaction Volume	185 µL	Same
Expected Values	5 - 30 U/L	Same
Measuring Range	4 - 480 U/L	Same
Sample Stability	Specimen is stable for 7 days at 4-8°C and -20°C.	Same

ACE AST Reagent

AST	Candidate Device	Predicate Device K930104 (ACE AST)
Intended Use/ Indications for Use	The ACE AST Reagent is intended for the quantitative determination of aspartate aminotransferase activity.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	**Serum**
Sample Volume	13 µL	Same
Reaction Volume	185 µL	Same
Expected Values	7 - 31 U/L	Same
Measuring Range	4 - 450 U/L	Same
Sample Stability	Specimen activity is stable for 28 days at 4°C and at least one year at -20°C	Same

Performance Data:

In-House Precision – Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Precision: Serum vs. Plasma – ACE Alkaline Phosphatase Reagent

Precision (SD, %CV)									
ALP (n=20)	ACE			*Alera*			Axcel		
	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total
Serum Low	92	1.2, 1.3%	1.9, 2.0%	91	0.8, 0.9%	2.0, 2.2%	90	1.2, 1.3%	2.1, 2.3%
Serum Mid	649	6.3, 1.0%	8.6, 1.3%	642	6.4, 1.0%	6.4, 1.0%	645	6.8, 1.0%	6.9, 1.1%
Serum High	1198	20.2, 1.7%	20.8, 1.7%	1190	5.6, 0.5%	8.7, 0.7%	1194	6.1, 0.5%	7.9, 0.7%
Plasma Low	76	1.9, 2.5%	2.8, 3.7%	75	0.8, 1.1%	3.4, 4.6%	74	1.1, 1.5%	3.7, 5.1%
Plasma Mid	614	5.8, 0.9%	24.4, 4.0%	609	5.1, 0.8%	20.2, 3.3%	613	3.4, 0.6%	20.5, 3.3%
Plasma High	1163	6.8, 0.6%	33.5, 2.9%	1149	5.9, 0.5%	32.9, 2.9%	1155	7.6, 0.7%	35.7, 3.1%

In-House Precision: Serum vs. Plasma – ACE Amylase Reagent

Precision (SD, %CV)									
AMY (n=20)	ACE			*Alera*			Axcel		
	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total
Serum Low	46	0.7, 1.5%	0.9, 2.1%	46	1.0, 2.1%	1.5, 3.3%	46	1.2, 2.6%	1.6, 3.4%
Serum Mid	830	9.2, 1.1%	11.5, 1.4%	825	5.1, 0.6%	11.9, 1.4%	826	9.2, 1.1%	11.9, 1.4%
Serum High	1597	15.0, 0.9%	19.8, 1.2%	1577	9.9, 0.6%	29.4, 1.9%	1586	8.5, 0.5%	18.6, 1.2%
Plasma Low	41	0.7, 1.8%	1.3, 3.2%	42	0.5, 1.3%	1.5, 3.5%	41	1.0, 2.5%	2.5, 6.0%
Plasma Mid	806	8.1, 1.0%	12.5, 1.5%	801	4.4, 0.5%	13.1, 1.6%	805	5.3, 0.7%	12.2, 1.5%
Plasma High	1604	15.4, 1.0%	29.3, 1.8%	1596	18.8, 1.2%	33.8, 2.1%	1604	21.6, 1.3%	25.0, 1.6%

Performance Data:

In-House Precision – Serum vs. Plasma

In-House Precision: Serum vs. Plasma – ACE ALT Reagent

Precision (SD, %CV)									
ALT (n=24)	ACE			*Alera*			Axcel		
	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total
Serum Low	36	0.9, 2.6%	1.4, 4.0%	36	0.6, 1.7%	1.2, 3.3%	37	1.1, 3.1%	1.4, 3.7%
Serum Mid	114	1.3, 1.2%	1.8, 1.6%	114	1.3, 1.1%	2.2, 2.0%	115	1.4, 1.2%	2.3, 2.0%
Serum High	216	2.9, 1.4%	4.0, 1.9%	216	1.8, 0.8%	3.5, 1.6%	218	1.4, 0.6%	3.2, 1.5%
Plasma Low	32	0.9, 2.7%	1.3, 4.0%	32	0.8, 2.6%	1.5, 4.7%	34	1.0, 2.9%	1.4, 4.1%
Plasma Mid	112	1.1, 1.0%	1.5, 1.4%	112	0.9, 0.8%	1.1, 1.0%	113	1.0, 0.9%	1.5, 1.4%
Plasma High	219	1.1, 0.5%	1.6, 0.7%	219	2.1, 0.9%	3.0, 1.4%	222	1.7, 0.7%	2.7, 1.2%

In-House Precision: Serum vs. Plasma – ACE AST Reagent

Precision (SD, %CV)									
AST (n=24)	ACE			*Alera*			Axcel		
	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total	Mean (U/L)	Within-Run	Total
Serum Low	26	0.7, 2.6%	1.2, 4.5%	25	0.7, 2.7%	0.8, 3.3%	25	1.1, 4.3%	1.4, 5.7%
Serum Mid	155	1.3, 0.8%	2.7, 1.8%	155	1.0, 0.7%	2.8, 1.8%	155	0.7, 0.5%	2.3, 1.5%
Serum High	301	3.5, 1.2%	4.8, 1.6%	302	2.2, 0.7%	4.0, 1.3%	304	2.7, 0.9%	4.1, 1.4%
Plasma Low	26	0.8, 3.2%	1.4, 5.4%	26	0.6, 2.5%	1.0, 3.7%	26	0.9, 3.5%	1.0, 4.0%
Plasma Mid	157	1.6, 1.0%	2.3, 1.4%	157	1.5, 0.9%	1.7, 1.1%	158	1.4, 0.9%	2.0, 1.3%
Plasma High	304	3.5, 1.2%	4.5, 1.5%	303	2.6, 0.9%	3.9, 1.3%	305	3.2, 1.1%	4.3, 1.4%

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Matrix Comparison: Serum vs. Plasma – ACE ALP Reagent

System	Range	Results - Serum vs. Plasma	
ACE	9 - 1274 U/L	Slope:	0.998
		Intercept:	-8.3
108 pairs		Correlation:	0.9980
		Std. Error Est:	13.5
		Confidence Interval Slope:	0.986 to 1.010
		Confidence Interval Intercept:	-11.5 to -5.1
ACE *Alera*	9 - 1202 U/L	Slope:	0.983
		Intercept:	-6.4
108 pairs		Correlation:	0.9952
		Std. Error Est:	20.2
		Confidence Interval Slope:	0.965 to 1.002
		Confidence Interval Intercept:	-11.2 to -1.6
ACE Axcel	11 - 1222 U/L	Slope:	1.017
		Intercept:	-6.5
62 pairs		Correlation:	0.9982
		Std. Error Est:	14.5
		Confidence Interval Slope:	1.001 to 1.033
		Confidence Interval Intercept:	-11.1 to -1.8

In-House Matrix Comparison: Serum vs. Plasma – ACE Amylase Reagent

System	Range	Results - Serum vs. Plasma	
ACE	11 – 1766 U/L	Slope:	0.977
		Intercept:	1.7
104 pairs		Correlation:	0.9995
		Std. Error Est:	8.8
		Confidence Interval Slope:	0.970 to 0.983
		Confidence Interval Intercept:	-0.2 to 3.6
ACE *Alera*	11 - 1703 U/L	Slope:	0.979
		Intercept:	0.9
101 pairs		Correlation:	0.9994
		Std. Error Est:	9.0
		Confidence Interval Slope:	0.972 to 0.986
		Confidence Interval Intercept:	-1.0 to 2.9
ACE Axcel	10 - 1890 U/L	Slope:	0.994
		Intercept:	-1.76
52 pairs		Correlation:	0.9996
		Std. Error Est:	11.54
		Confidence Interval Slope:	0.986 to 1.002
		Confidence Interval Intercept:	-5.33 to 1.80

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

In-House Matrix Comparison: Serum vs. Plasma – ACE ALT Reagent

System	Range	Results - Serum vs. Plasma	
ACE	4 - 460 U/L	Slope:	1.003
		Intercept:	-3.6
54 pairs		Correlation:	0.9994
		Std. Error Est:	2.8
		Confidence Interval Slope:	0.994 to 1.013
		Confidence Interval Intercept:	-4.5 to -2.8
ACE *Alera*	5 - 463 U/L	Slope:	1.000
		Intercept:	-3.6
52 pairs		Correlation:	0.9986
		Std. Error Est:	4.3
		Confidence Interval Slope:	0.985 to 1.015
		Confidence Interval Intercept:	-4.9 to -2.2
ACE Axcel	6 - 469 U/L	Slope:	0.985
		Intercept:	-3.35
56 pairs		Correlation:	0.9993
		Std. Error Est:	2.94
		Confidence Interval Slope:	0.976 to 0.995
		Confidence Interval Intercept:	-4.24 to -2.47

In-House Matrix Comparison: Serum vs. Plasma – ACE AST Reagent

System	Range	Results - Serum vs. Plasma	
ACE	4 - 404 U/L	Slope:	0.981
		Intercept:	0.7
53 pairs		Correlation:	0.9992
		Std. Error Est:	3.2
		Confidence Interval Slope:	0.971 to 0.992
		Confidence Interval Intercept:	-0.3 to 1.7
ACE *Alera*	4 - 396 U/L	Slope:	0.999
		Intercept:	-0.6
52 pairs		Correlation:	0.9989
		Std. Error Est:	3.9
		Confidence Interval Slope:	0.985 to 1.012
		Confidence Interval Intercept:	-1.9 to 0.6
ACE Axcel	4 - 408 U/L	Slope:	1.001
		Intercept:	0.22
52 pairs		Correlation:	0.9989
		Std. Error Est:	3.97
		Confidence Interval Slope:	0.987 to 1.014
		Confidence Interval Intercept:	-1.04 to 1.49

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

(Note: Please refer to previously cleared submissions k113436 (ALP and Amylase) and k113382 (ALT and AST) for ACE Axcel POL data)

ALP			ACE Results U/L SD, %CV		Mean	ACE *Alera* Results U/L SD, %CV	
Lab	Sample	Mean	Within-Run	Total		Within-Run	Total
In-House	1	59	1.2	1.4	60	1.1	1.3
			2.0%	2.5%		1.8%	2.1%
POL 1	1	55	0.7	2.3	56	0.8	1.7
			1.4%	4.1%		1.4%	3.0%
POL 2	1	54	0.9	1.6	59	1.2	2.1
			1.6%	2.9%		2.0%	3.5%
POL 3	1	57	1.0	1.5	56	1.4	3.0
			1.8%	2.6%		2.5%	5.4%
In-House	2	648	5.5	6.7	653	4.5	7.0
			0.8%	1.0%		0.7%	1.1%
POL 1	2	632	6.9	13.4	626	7.4	16.7
			1.1%	2.1%		1.2%	2.7%
POL 2	2	631	6.2	11.9	659	4.2	18.0
			1.0%	1.9%		0.6%	2.7%
POL 3	2	642	3.7	8.6	640	5.9	21.9
			0.6%	1.3%		0.9%	3.4%
In-House	3	1191	7.0	10.7	1192	9.4	13.4
			0.6%	0.9%		0.8%	1.1%
POL 1	3	1145	10.3	23.0	1135	19.0	25.0
			0.9%	2.0%		1.7%	2.2%
POL 2	3	1159	12.8	17.2	1209	9.6	29.3
			1.1%	1.5%		0.8%	2.4%
POL 3	3	1185	6.2	7.3	1165	6.6	37.2
			0.5%	0.6%		0.6%	3.2%

Performance Data at POL:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

AMY			ACE Results U/L SD, %CV		Mean	ACE *Alera* Results U/L SD, %CV	
Lab	**Sample**	**Mean**	**Within-Run**	**Total**		**Within-Run**	**Total**
In-House	1	39	1.0	1.3	39	0.8	1.4
			2.7%	3.2%		2.1%	3.5%
POL 1	1	37	0.5	1.2	38	0.9	1.7
			1.5%	3.2%		2.4%	4.4%
POL 2	1	39	0.7	0.9	40	1.3	1.3
			1.9%	2.4%		3.2%	3.2%
POL 3	1	39	0.6	1.1	39	1.0	1.1
			1.6%	2.7%		2.5%	2.8%
In-House	2	741	7.1	8.6	747	4.4	7.3
			1.0%	1.2%		0.6%	1.0%
POL 1	2	725	4.6	11.5	723	4.7	7.0
			0.6%	1.6%		0.6%	1.0%
POL 2	2	727	7.4	8.2	770	4.3	6.1
			1.0%	1.1%		0.6%	0.8%
POL 3	2	737	9.6	11.3	747	5.8	7.4
			1.3%	1.5%		0.8%	1.0%
In-House	3	1429	7.5	13.1	1437	11.6	12.8
			0.5%	0.9%		0.8%	0.9%
POL 1	3	1389	18.1	27.8	1388	19.5	21.6
			1.3%	2.0%		1.4%	1.6%
POL 2	3	1401	22.4	23.8	1500	10.3	11.7
			1.6%	1.7%		0.7%	0.8%
POL 3	3	1410	12.9	15.7	1435	8.4	14.4
			0.9%	1.1%		0.6%	1.0%

Performance Data at POL:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

ALT			ACE Results U/L SD, %CV		Mean	ACE *Alera* Results U/L SD, %CV	
Lab	Sample	Mean	Within-Run	Total		Within-Run	Total
In-House	1	33	0.9	1.3	32	1.1	1.2
			2.7%	3.9%		3.5%	3.9%
POL 1	1	26	0.5	1.7	28	1.4	2.4
			1.9%	6.4%		5.1%	8.4%
POL 2	1	27	0.9	1.8	26	0.9	2.1
			3.2%	6.7%		3.6%	8.2%
POL 3	1	30	1.0	1.7	29	2.1	2.4
			3.4%	5.7%		7.5%	8.4%
In-House	2	191	4.8	4.8	190	4.0	4.1
			2.5%	2.5%		2.1%	2.1%
POL 1	2	189	1.2	1.6	193	1.7	2.0
			0.6%	0.8%		0.9%	1.0%
POL 2	2	192	2.3	5.9	194	2.2	2.5
			1.2%	3.1%		1.1%	1.3%
POL 3	2	188	2.9	3.9	195	3.5	5.0
			1.5%	2.1%		1.8%	2.6%
In-House	3	309	2.2	3.7	307	4.0	4.1
			0.7%	1.2%		1.3%	1.3%
POL 1	3	304	4.0	4.4	309	3.1	3.6
			1.3%	1.4%		1.0%	1.2%
POL 2	3	311	2.9	10.2	314	2.3	2.6
			0.9%	3.3%		0.7%	0.8%
POL 3	3	303	3.4	5.0	310	8.5	9.1
			1.1%	1.6%		2.8%	3.0%

Performance Data at POL:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

AST			ACE Results U/L SD, %CV		Mean	ACE *Alera* Results U/L SD, %CV	
Lab	**Sample**	**Mean**	**Within-Run**	**Total**		**Within-Run**	**Total**
In-House	1	28	1.4	2.1	28	1.2	1.7
			5.1%	7.4%		4.5%	6.0%
POL 1	1	23	0.9	1.4	26	1.0	1.3
			3.7%	6.0%		3.8%	5.1%
POL 2	1	28	1.5	1.7	27	2.0	2.4
			5.6%	6.0%		7.5%	8.9%
POL 3	1	26	0.7	2.0	29	2.9	2.9
			2.7%	7.7%		9.9%	9.9%
In-House	2	223	6.4	6.6	222	4.8	7.1
			2.9%	3.0%		2.2%	3.2%
POL 1	2	220	2.2	4.0	220	2.0	3.2
			1.0%	1.8%		0.9%	1.5%
POL 2	2	227	2.0	4.8	233	3.8	5.0
			0.9%	2.1%		1.6%	2.1%
POL 3	2	223	2.6	4.7	229	5.3	7.2
			1.2%	2.1%		2.3%	3.2%
In-House	3	410	6.3	6.8	406	2.9	6.8
			1.5%	1.7%		0.7%	1.7%
POL 1	3	416	5.0	5.5	416	7.8	9.2
			1.2%	1.3%		1.9%	2.2%
POL 2	3	420	9.0	10.2	428	5.1	5.6
			2.2%	2.4%		1.2%	1.3%
POL 3	3	407	3.9	7.3	417	8.2	12.1
			0.9%	1.8%		2.0%	2.9%

Performance Data:

Method Comparison - POL on ACE

POL – Method Comparison for ACE Clinical Chemistry System

Reagent	Statistic	In-House ACE (x) vs. POL 1 ACE (y)	In-House ACE (x) vs. POL 2 ACE (y)	In-House ACE(x) vs. POL 3 ACE (y)
ALP	n	49	50	50
	Range	58 to 1199	58 to 1199	58 to 1199
	Regression	y = 0.989x - 9.5	y = 0.977x - 7.9	y = 0.982x - 2.8
	Correlation	0.9987	0.9997	0.9995
	Std. Error Est.	12.4	5.9	7.4
	CI Slope	0.975 to 1.004	0.970 to 0.984	0.973 to 0.990
	CI Intercept	-13.8 to -5.1	-9.9 to -5.8	-5.4 to -0.2
AMY	n	51	51	51
	Range	28 to 1732	28 to 1732	28 to 1732
	Regression	y = 0.970x + 1.5	y = 0.973x + 3.6	y = 0.974x + 3.9
	Correlation	0.9995	0.9998	0.9998
	Std. Error Est.	11.1	7.5	7.4
	CI Slope	0.962 to 0.979	0.967 to 0.978	0.968 to 0.980
	CI Intercept	-2.1 to 5.2	1.1 to 6.0	1.5 to 6.3
ALT	n	44	47	49
	Range	6 to 442	6 to 442	6 to 442
	Regression	y = 1.006x - 4.7	y = 1.021x - 4.0	y = 0.982x - 2.3
	Correlation	0.9978	0.9993	0.9981
	Std. Error Est.	6.5	3.7	5.7
	CI Slope	0.985 to 1.026	1.010 to 1.033	0.964 to 0.999
	CI Intercept	-6.9 to -2.4	-5.2 to -2.8	-4.1 to -0.4
AST	n	50	50	50
	Range	6 to 413	6 to 413	6 to 413
	Regression	y = 0.999x - 0.6	y = 1.019x + 2.4	y = 0.992x + 0.6
	Correlation	0.9993	0.9989	0.9994
	Std. Error Est.	3.9	4.9	3.6
	CI Slope	0.988 to 1.010	1.005 to 1.033	0.982 to 1.003
	CI Intercept	-1.9 to 0.6	0.9 to 4.0	-0.6 to 1.7

Performance Data at POL:

Method Comparison - POL on ACE *Alera*

POL – Method Comparison for ACE *Alera* Clinical Chemistry System

Reagent	Statistic	In-House ACE (x) vs. POL 1 Alera (y)	In-House ACE (x) vs. POL 2 Alera (y)	In-House ACE (x) vs. POL 3 Alera (y)
ALP	n	50	50	50
	Range	58 to 1199	58 to 1199	58 to 1199
	Regression	y = 0.997x - 4.6	y = 1.029x - 4.1	y = 1.010x - 6.6
	Correlation	0.9992	0.9991	0.9986
	Std. Error Est.	10.1	10.8	13.0
	CI Slope	0.985 to 1.008	1.016 to 1.041	0.995 to 1.025
	CI Intercept	-8.1 to -1.1	-7.9 to -0.4	-11.2 to -2.1
AMY	n	51	51	51
	Range	28 to 1732	28 to 1732	28 to 1732
	Regression	y = 0.960x + 3.0	y = 1.010x + 5.8	y = 0.990x + 3.7
	Correlation	0.9991	0.9995	0.9995
	Std. Error Est.	15.1	11.7	11.3
	CI Slope	0.948 to 0.971	1.001 to 1.018	0.981 to 0.999
	CI Intercept	-1.9 to 7.9	2.0 to 9.6	0.0 to 7.4
ALT	n	50	48	50
	Range	6 to 442	6 to 442	6 to 442
	Regression	y = 1.019x - 0.5	y = 1.012x - 3.5	y = 0.970x + 2.4
	Correlation	0.9986	0.9985	0.9977
	Std. Error Est.	5.1	5.3	6.1
	CI Slope	1.003 to 1.035	0.995 to 1.028	0.951 to 0.990
	CI Intercept	-2.1 to 1.1	-5.3 to -1.8	0.5 to 4.4
AST	n	50	50	50
	Range	6 to 413	6 to 413	6 to 413
	Regression	y = 1.028x + 1.4	y = 1.040x + 0.5	y = 1.004x + 1.8
	Correlation	0.9995	0.9992	0.9995
	Std. Error Est.	3.5	4.3	3.3
	CI Slope	1.018 to 1.037	1.027 to 1.052	0.994 to 1.013
	CI Intercept	0.3 to 2.5	-0.8 to 1.9	0.8 to 2.9

Performance Data:

ACE *Alera*

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE *Alera* Clinical Chemistry Systems

Detection Limits - ACE *Alera* Clinical Chemistry System

ACE *Alera*	ALP	Amylase	ALT	AST
LoB (U/L)	2.8	0.2	1.6	2.2
LoD (U/L)	4.8	0.9	3.1	3.3
LoQ (U/L)	4.8	5.6	4.1	3.3

Linearity - ACE *Alera* Clinical Chemistry System

ACE Reagents	Low level tested	Upper level tested	Linear to:	Linear Regression Equation	R^2
ALP	4.0 U/L	1401 U/L	1400 U/L	y = 0.998x – 0.5	0.9993
Amylase	4.0 U/L	2012 U/L	1900 U/L	y = 1.013x + 0.2	0.9974
ALT	3.1 U/L	504 U/L	480 U/L	y = 1.007x - 0.17	0.9992
AST	3.0 U/L	491 U/L	450 U/L	y = 1.013x + 0.24	0.9992

Performance Data:

ACE *Alera*

Interferences - ACE *Alera* Clinical Chemistry System

Interferents on ACE *Alera*	No Significant Interference at or below:			
	ALP	Amylase	ALT	AST
Icterus	70.6 mg/dL	30.0 mg/dL	50 mg/dL	50 mg/dL
Hemolysis	62.5 mg/dL	62.5 mg/dL	500 mg/dL	62.5 mg/dL
Lipemia	1000 mg/dL	1000 mg/dL	419 mg/dL	439 mg/dL
Ascorbic Acid	6 mg/dL	6 mg/dL	6 mg/dL	6 mg/dL

Precision - ACE *Alera* Clinical Chemistry System

on ACE *Alera*		*Precision (SD, %CV)*		
		Mean	Within-Run	Total
ALP U/L	Low	43	0.9 , 2.2%	1.9 , 4.5%
	Mid	164	2.8 , 1.7%	5.5 , 3.4%
	High	339	5.3 , 1.6%	8.9 , 2.6%
AMYLASE U/L	Low	45	0.9 , 2.1%	1.5 , 3.3%
	Mid	139	1.7 , 1.2%	3.9 , 2.8%
	High	311	5.0 , 1.6%	7.7 , 2.5%
ALT U/L	Low	37	1.2 , 3.3%	1.8 , 4.9%
	Mid	181	2.2 , 1.2%	3.2 , 1.8%
	High	320	5.2 , 1.6%	5.2 , 1.6%
AST U/L	Low	34	1.1 , 3.3%	1.5 , 4.4%
	Mid	175	3.5 , 2.0%	3.6 , 2.1%
	High	312	4.8 , 1.5%	4.9 , 1.6%

Performance Data:

ACE *Alera*

Method Comparison - ACE *Alera* Clinical Chemistry System

In-House ACE (x) vs. In-House ACE *Alera* (y)

	ALP	Amylase	ALT	AST
n	60	57	50	50
Range (U/L)	9 to 1199	10 to 1732	6 to 442	6 to 413
Slope	0.991	0.995	0.988	1.006
Intercept	0.5	2.9	1.3	1.5
Correlation Coefficient	0.9999	0.9998	0.9999	0.9998
Std. Error	3.5	6.6	1.6	1.9
CI Slope	0.987 to 0.995	0.990 to 1.000	0.983 to 0.992	1.001 to 1.012
CI Intercept	-0.5 to 1.6	0.9 to 4.9	0.8 to 1.8	0.9 to 2.2

Conclusions:

Based on the foregoing data, the device is safe and effective for use in clinical laboratories and physician office laboratories. These data indicate substantial equivalence for lithium heparin plasma sample collection tubes to the predicate device's use of serum sample collection tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

Alfa Wassermann Diagnostic Technologies, LLC
C/O Hyman Katz, Ph.D.
4 Henderson Drive
WEST CALDWELL NJ 07006

Re: K131351
Trade/Device Name: ACE Alkaline Phosphatase Reagent
ACE Amylase Reagent
ACE ALT Reagent
ACE AST Reagent
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: II
Product Code: CJE, CIJ, CKA, CIT
Dated: July 8, 2013
Received: July 9, 2013

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __k131351_____

Device Name: ACE Alkaline Phosphatase Reagent

Indications for Use: The ACE Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Amylase Reagent

Indications for Use: The ACE Amylase Reagent is intended for the quantitative determination of α-amylase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas). This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k)_____k131351_____

Indications for Use

510(k) Number (if known): ___k131351_____

Device Name: ACE ALT Reagent

Indications for Use: The ACE ALT Reagent is intended for the quantitative determination of alanine aminotransferase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Alanine aminotransferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE AST Reagent

Indications for Use: The ACE AST Reagent is intended for the quantitative determination of aspartate aminotransferase activity in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Measurements of aspartate aminotransferase are used in the diagnosis and treatment of certain types of liver and heart disease. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Ruth A. Chesler -S

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